UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Johns v. CR Bard et al.,
Case No. 2:18-cv-1509

MOTIONS IN LIMINE OPINION AND ORDER NO. 7

Plaintiff Steven Johns and Defendants C.R. Bard, Inc. and Davol, Inc. filed various motions in limine to exclude evidence in this case. Now before the Court are nonparty the Americas Hernia Society Quality Collaborative Foundation's ("AHSQCF") Motion in Limine Re: Use of Reports Prepared by AHSQCF (ECF No. 180), Defendants' Motion in Limine No. 12 to Exclude Evidence and Argument Concerning Medical Device Reports and Complaints related to Patients Other than Plaintiff (ECF No. 213), Plaintiff's Motion in Limine No. 23 to Exclude Arguments and Evidence Relating to the Number of Devices Sold or Implanted, or that Hernia Mesh Products are Lifesaving Devices (ECF No. 247), and Plaintiff's Motion in Limine No. 7 to Exclude Any Percentage or Comparative Analysis of Adverse Events (ECF No. 243). The Court reserved judgment on these motions and stated this written decision was to follow. (ECF No. 332 at PageID #17887; ECF No. 345 at PageID #18586.)

I. Background[1]

This case is the first bellwether trial, selected from thousands of cases in this multidistrict

[1] The Court assumes that the parties and other interested readers are familiar with the history of this case. For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. (ECF No. 309.)

litigation ("MDL"), alleging "that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)[2] This includes the Ventralight ST, the device implanted in Plaintiff. The Ventralight ST is a prescription medical device used for hernia repairs. (ECF No. 309 at PageID #16717.) The Food and Drug Administration ("FDA") cleared it for use through the premarket notification § 510(k) process in 2010 and later cleared it for use with the Echo Positioning System in 2011. It is a multicomponent device made of a mesh, which consists of polypropylene, polyglycolic acid ("PGA") fibers, and a bioresorbable coating called "Sepra Technology" ("ST"). The ST-coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed against the fascia because the uncoated side maximizes tissue attachment and thus supports the hernia repair. (*Id.*)

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralight ST device. Plaintiff claims that Defendants knew that polypropylene is unsuitable for permanent implantation in the human body and that the PGA fibers created an increased inflammatory response. (*Id.*) The crux of Plaintiff's claims is that the ST coating on Ventralight ST devices resorbs too quickly. This leads to the exposure of bare polypropylene to internal organs and tissues, increasing the risk of potential complications. Plaintiff alleges that this occurrence led to omental adhesions after his laparoscopic hernia repair surgery in 2015. The adhesions were diagnosed during a subsequent laparoscopic surgery in October 2016 by Plaintiff's implanting surgeon. (*Id.* at PageID #16740, 16746.)[3] After summary

[2] Unless otherwise noted, record citations are to the docket for this case, No. 18-cv-01509.

[3] The Court granted Defendants' motion for summary judgment on Plaintiff's other alleged injuries because Plaintiff failed to demonstrate a material fact dispute regarding causation. (ECF No. 309 at PageID #16740.)

judgment, the following claims remain for trial: design defect, under negligence and strict liability theories; failure to warn, under negligence and strict liability theories; breach of express warranty; breach of implied warranty; breach of implied warranty of merchantability; negligent misrepresentation; and punitive damages. (*Id.* at PageID #16727–65.) Now, various motions in limine and other evidentiary motions are ripe for adjudication.

This opinion addresses four motions in limine that concern the use of data—data from AHSQCF, the use of Medical Device Reports ("MDRs"), tallies of the number of Ventralight ST devices sold and implanted, and percentages and comparative analytics of adverse events. (ECF Nos. 180, 213, 247, 243 (respectively).) On August 27, 2020, the Court considered AHSQCF's motion in limine and Plaintiff's Motion in Limine No. 7 and ordered Plaintiff to submit the AHSQCF data it planned to admit at trial, outlining the purposes for which it would be used. (ECF No. 306 at PageID #16688; ECF No. 311 at PageID# 16818–24.) The Court addressed these two motions in limine, along with Defendants' Motion in Limine No. 12, regarding MDRs, and Plaintiff's Motion in Limine No. 23, concerning sales and implantation numbers, during a second hearing on September 10, 2020. (ECF No. 345 at PageID #18567–87.) Plaintiff was also ordered to submit examples of the MDRs, (*id.* at PageID #18577–79), and the parties were then permitted to submit supplemental briefing regarding the MDRs, (ECF Nos. 348–50). The Court reserved judgment upon these four motions. (ECF No. 332 at PageID #17887.)

II. Legal Standards

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of

trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Ind. Ins. Co.*, 326 F. Supp. 2d at 846; *see also Koch*, 2 F. Supp. 2d at 1388. The denial, in whole or in part, of a motion in limine does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. "Irrelevant evidence is" inadmissible. Fed. R. Evid. 402. A court may exclude relevant evidence under Federal Rule of Evidence 403 "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Evidentiary rulings are made subject to the district court's sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*, 295 F.3d 565, 576 (6th Cir. 2002) ("In reviewing the trial court's decision for an abuse of

discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.").

III. Analysis

A. AHSQCF's Motion in Limine Re: Use of Reports Prepared by AHSQCF

AHSQCF, a nonparty to this litigation, initially filed its motion in limine arguing that because Plaintiff had not specified how he would use AHSQCF's reports pursuant to Magistrate Judge Jolson's March 16, 2020 order, Plaintiff did not need the reports for litigation and an order prohibiting their use was appropriate. (ECF No. 180 at PageID #10652.) Plaintiff maintains that he has complied with the order and points to his counsel's email stating that AHSQCF's reports would be "use[d] as any other longitudinal outcomes analysis and real-time claims data," such as "comparison of adverse event [sic] for products involving Sepra Technology versus non-ST products," among others. (ECF No. 200 at PageID #11621.) Ultimately, the Court ordered Plaintiff to submit for in camera review the AHSQCF reports it intended to use and for Plaintiff to specify the uses at trial for this evidence. (ECF No. 306 at PageID #16688, ECF No. 311 at PageID #16820.) AHSQCF also argues that the Plaintiffs' Steering Committee ("PSC") should be ordered to pay the value of a licensing fee to AHSQCF if its reports are permitted to be admitted.

1. Admissibility

Plaintiff plans to use the AHSQCF data to demonstrate three facts. First, Plaintiff claims that Defendants had knowledge that the method used to implant the Ventralight ST in Plaintiff, laparoscopic intra-peritoneal mesh placement or intra-peritoneal onlay mesh ("IPOM") procedures, had a higher likelihood of causing adhesions. Second, the five-year longitudinal data shows that this method of implantation for the Ventralight ST has no benefits over other methods

in terms of patient pain, hernia recurrence, and adhesions. Finally, the thirty-day data regarding IPOM procedures with Sepramesh devices generally shows that the IPOM procedure has no better benefits than other methods in relation to hernia recurrence, seroma formation, and patient pain. (ECF No. 316 at PageID #16874–78.) In response, AHSQCF contends that these uses are prohibited in light of this Court's summary judgment opinion and order and that using the data as AHSQCF has collected it misuses the data because the data has not been risk-adjusted. (ECF No. 338 at PageID #18476–80.) Defendants generally agree with AHSQCF. (ECF Nos. 199, 338-2.)

At this stage of the briefing, it appears that the core of AHSQCF's motion is whether its data is relevant under Rule 401 and likely to confuse or mislead the jury as prohibited by Rule 403. Because the Court granted summary judgment on Plaintiff's claims alleging pain and hernia reoccurrence as a result of implantation of the Ventralight ST and only Plaintiff's claims premised upon adhesions remain (ECF No. 309 at PageID #16740), the AHSQCF data is inadmissible to show that the Ventralight ST or Sepramesh IPOM procedures had higher hernia reoccurrence or reports of pain. This leaves the following uses: Defendants' notice that IPOM procedures with the Ventralight ST led to complications including adhesions and that IPOM procedures with Ventralight ST or Sepramesh led to more adverse outcomes in relation to adhesions than non-Bard devices.[4]

AHSQCF primarily contends that the AHSQCF data as Plaintiff intends to rely on it is statically unsound and misleading for a variety of reasons. (ECF No. 338 at PageID #18478.) For example, AHSQCF argues that Plaintiff's attempts to rely on the data to compare outcomes with Ventralight and Sepramesh devices and non-Defendant devices are misleading because there has

[4] It is unclear if the AHSQCF data that Plaintiff points to addresses adhesions in any manner based on the exhibits accompanying the briefing. But in the interests of judicial efficiency, the Court presumes that it may.

been no risk-adjustment. (*Id.*) Risk adjustment means that "only like-cases [sic] are compared to like-cases [sic]." (*Id.*) To illustrate this, AHSQCF quotes deposition testimony explaining that the outcome for a seventy-year-old obese patient with a twenty-centimeter hernia cannot be meaningfully compared to that of a thirty-year-old patient of normal weight with a one-centimeter hernia. (*Id.*)

Shortcomings of data go to the weight of the evidence, not its admissibility. In *United States v. Weinstock*, the Sixth Circuit rejected the defendant's argument that data charts were unreliable and thus excludable under Rule 403 because the subjects of the chart data could not remember certain details. 153 F.3d 272, 278 (6th Cir. 1998). The Sixth Circuit concluded that this went to "the weight [the jury] should give the document." *Id.* And the Ninth Circuit, though not binding upon this Court, has explicitly concluded that critiques of data and statistical studies do "not render[statistical evidence] irrelevant under Rule 402" because "objections to a study's completeness generally go to 'the weight, not the admissibility of the statistical evidence.'" *Obrey v. Johnson*, 400 F.3d 691, 695 (9th Cir. 2005) (quoting *Mangold v. Cal. Pub. Utils. Comm'n*, 67 F.3d 1470, 1476 (9th Cir. 1995)).

Even in relation to the admissibility of expert testimony, which expressly requires a showing of reliability prior to admission, Fed. R. Evid. 702(c), (d), courts have declined to exclude expert testimony based on the rigor of data interpretation barring "a significant error in application." *E.g.*, *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 530–31 (6th Cir. 2008) (collecting Sixth Circuit cases); *McLean v. 988011 Ontario, Ltd.*, 224 F.3d 797, 801 (6th Cir. 2000) ("An expert's opinion, where based on assumed facts, must find some support for those assumptions in the record. However, mere 'weaknesses in the factual basis of an expert witness' opinion . . . bear on the weight of the evidence rather than on its admissibility.'" (quoting *United*

States v. L.E. Cooke Co., 991 F.2d 336, 342 (6th Cir.1993)) (internal citations omitted)). The appropriate weight given to expert testimony, considering its accuracy and methodology, is a jury question. *United States v. Bonds*, 12 F.3d 540, 563–64 (6th Cir. 1993) (considering the failure of the FBI to account for the "ethnic substructure" of the DNA pattern as a matter of weight not admissibility). Other circuits have reached similar conclusions as to the reliability of expert testimony based upon data. *See, e.g.*, *Manpower Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 807–08 (7th Cir. 2013) (addressing the "selection of variables to include in a regression analysis"). Under these circumstances, "arguments about the accuracy of [the expert's] conclusion [are] appropriately left to '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction of the burden of proof,' rather than exclusion." *In re E.I. DuPont De Nemours & Co. C-8 Pers. Inj. Litig.*, 337 F. Supp. 3d 728, 743 (S.D. Ohio 2015) (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 596 (1993)). There is no basis for requiring statistical perfection of the data at issue here.

AHSQCF and Defendants point to a statistical unreliability of the AHSQCF data, which the jury is more than capable of evaluating at trial. The materiality and probative value of the AHSQCF data as to Defendants' notice and the risks accompanying the Ventralight ST and Sepramesh in IOPM procedures in relation to other non-Defendant meshes is not significantly outweighed by the risk that the jury will misinterpret meaning of the data. AHSQCF's and Defendants' attacks upon the data are persuasive and relatively simple to follow. Undoubtedly, Defendants will attack Plaintiff's presentation of AHSQCF data by showing that the data compares apples to oranges (or thirty-year-olds to seventy-year-olds, or one-centimeter to twenty-centimeter hernias). *Cf. Int'l Brotherhood of Teamsters v. United States*, 431 U.S. 324, 340 (1977) ("We caution only that statistics are not irrefutable; they come in infinite variety and, like any other kind of evidence, they may be rebutted."). The importance of comparing similar patients to draw

meaningful conclusions from data is not beyond the reach of the average juror. Any risk of misleading the jury is sure to be tempered by vigorous attack on Plaintiff's use of the data, which even Plaintiff acknowledges has shortcomings. *See infra* Part III.D.

Neither AHSQCF nor Defendants cite binding contrary authority. AHSQCF cites a case addressing expert testimony, *Svindland v. Nemours Found.*, Nos. 05–417, 05–441, 2009 WL 1407749 (E.D. Pa. May 18, 2009), but the approach in this circuit is not to exclude data that was not risk-adjusted as irrelevant; rather, the approach is to let the jury weigh the reliability of the evidence, as set forth *supra*. AHSQCF's other authorities are inapposite. For example, it cites *United States v. Olvis*, which addresses a selective-prosecution claim—an entirely different question than the evidentiary one here. 97 F.3d 739, 744–45 (4th Cir. 1996). And Defendants noticeably fail to provide a single legal authority supporting exclusion of statistical and data-driven evidence for which some critiques exist.

AHSQCF argues that "the balance of interests justifies entry of an order prohibiting" use of its data (ECF No. 180 at PageID #10653), but this argument says nothing of relevance under Rule 401 or prejudice under Rule 403. AHSQCF points to the harm it will suffer if use of its reports is permitted in litigation, including a significant loss of physician participation, a decline in sponsorship support, and significant damage to its professional reputation. (*Id.* at PageID #10652.) There is no support for this position, however. AHSQCF cites *Massachusetts Eye & Ear Infirmary v. QLT Phototherapeutcs, Inc.*, 412 F.3d 215 (1st Cir. 2005), but this case addresses trade secrets claims under Massachusetts state law—not admissibility of evidence under the Federal Rules, *id.*at 238. In any case, the Court has already addressed these concerns in their proper context by granting AHSQCF's motion to seal. (ECF No. 359 at PageID #18785–89.)

AHSQCF also points to a decision addressing motions to quash subpoenas, *Medical Center*

Elizabeth Place, LLC v. Premier Health Partners, 294 F.R.D. 87 (S.D. Ohio 2013). However, the merits of a motion to quash a subpoena rely on a different inquiry. Relevance turns on materiality and probative value of evidence. Whether a subpoena should be quashed under Federal Rule of Civil Procedure 45 when matter is privileged or would subject a nonparty to an undue burden depends on (1) "whether the entity seeking protection has shown that the information sought is proprietary and that its disclosure might be harmful," (2) "whether the party seeking the discovery has established that the information is relevant and necessary to the underlying action," and (3) whether the balance between the party's need for discovery against the harm against the nonparty favors disclosure. *Medical Ctr.*, 294 F.R.D. at 92. This three-step inquiry addresses relevance, but Rule 401 does not consider whether evidence is proprietary or privileged. And importantly, this Court has already ordered AHSQCF disclose its data and reports in response to Plaintiff's subpoena. (ECF No. 364 at PageID #4721–22.)

Although these harms are no basis for prohibiting the admission of relevant evidence, AHSQCF's real concerns about harm resulting from use of its data in litigation do not evaporate simply because litigation has moved past discovery. Federal Rule of Evidence 102 requires fair application of the Rules. Fed. R. Evid. 102. The Court is cognizant of this as it has been throughout this litigation. For example, the Court has permanently sealed AHSQCF's reports (ECF No. 359 at PageID #18789) and permitted only three individuals on the PSC to have the ability to review the reports (ECF No. 364 at PageID #4721–22.) During trial, measures will be taken to ensure that this evidence remains confidential.

Finally, AHSQCF and Defendants argue that the percentages that Plaintiff calculates using AHSQCF data are misleading. (ECF No. 338 at PageID #18478–79; ECF No. 338-2 at PageID #18493.) For the reasons set forth below in response to Plaintiff's Motion in Limine No. 7,

AHSQCF's motion is granted in this regard. Plaintiff may not perform his own statistical analysis, though he may refer to AHSQCF's statistics and figures as represented in the AHSQCF reports. *See* Part III.D.

2. *Licensing Fees*

AHSQCF also argues that should the Court permit use of its data and reports, it should order the PSC to pay the value of its licensing fees. (ECF No. 180 at PageID #10653–54.) Rule 45 provides that when a subpoena requires a nonparty to "disclos[e] a trade secret or other confidential research, development, or commercial information," Fed. R. Civ. Pro. 45(d)(3)(B)(i), the court may "ensure [ ] that the subpoenaed person will be reasonably compensated," *id.* at (d)(3)(C)(ii). "What exactly is entailed by 'reasonable compensation' is left implicitly by the text of the rule to the court's discretion." 9A Fed. Prac. & Proc. Civ. § 2463.1 (WestLaw Oct. 2020 Update); *see also Klay v. All Defs.*, 425 F.3d 977, 984 (11th Cir. 2005). Only one circuit court has considered the propriety of awarding licensing fees under similar circumstances and concluded that because protective measures were taken during trial, none were appropriate. *Klay*, 425 F.3d at 984 ("Although reasonable compensation may require more than reimbursement for the costs of production, it need not always be so. The term 'reasonable compensation' is both broad and flexible.").

There is no indication that licensing fees should be awarded here. First, AHSQCF speculates as to any financial or property loss commensurate with its licensing fees. In *Klay*, the Eleventh Circuit concluded that because measures were taken at trial to preserve the confidentiality of the information, the disclosure did not harm the nonparty nor did it diminish its "opportunit[ies] to sell its intellectual property." *See id.* at 986. Such measures shall be taken here. Accordingly, AHSQCF is not entitled to licensing fees, or at the least, an award would be premature.

AHSQCF provides no countervailing authority. It first argues that this is an instance of noncommercial, noncompetitive harm and cites to *Cohen v. City of New York*, 255 F.R.D. 110 (S.D.N.Y. 2008). Though the court in *Cohen* did consider the loss of goodwill of the nonparty in the event of disclosure, it did so in relation to whether the information should be disclosed; it considered the loss of income separately and in relation to the commercial value of the information. *Id.* at 119–21; *see also Gonzales v. Google, Inc.*, 234 F.R.D. 674, 683–84 (N.D. Cal. 2006) (considering the potential loss of user trust in relation to *disclosure*, not compensation); *In re Silicone Gel Breast Implants Prod. Liab. Litig.*, No. CV 92-P-10000S, 1996 WL 1358526, at *1–3 (N.D. Al. Apr. 11, 1996) (denying plaintiff's motion to compel *disclosure* of data in a research database). Additionally, AHSQCF asserts that use of its data at trial would lead to a decrease in surgeon participation in data reporting, but it provides no evidence or citation to the record. (ECF No. 180 at PageID #10649.)

Even if AHSQCF did provide evidence of a noncommercial loss, however, it is unclear why it would be entitled to its licensing fees, which would be commensurate with a commercial loss, i.e. the lost opportunity to license use of its data. The Eleventh Circuit in *Klay*, which AHSQCF relies upon, expressly considered nonrivalrous compensation, explaining nonrivalrous compensation "will ordinarily be limited to the marginal cost incurred by that use . . . *even if the taking deprives the owner of the opportunity to sell the use of its property at a desired price*, because the 'one immutable principle in the law of just compensation . . . is that the value to the taker is not to be considered, only loss to the owner is to be valued.'" 425 F.3d at 985 (emphasis added) (citation omitted). Such a "windfall" to AHSQCF would be improper. *Id.*

For these reasons, AHSQCF's motion is granted in part and denied in part.

B. Defendants' Motion in Limine No. 12

In Defendants' Motion in Limine No. 12, Defendants seek exclusion of evidence and argument concerning medical device reports ("MDRs") and complaints related to patients other than Plaintiff, otherwise known as adverse event reports ("AERs"). (ECF No. 213 at PageID #11928.) Specifically, Defendants argue that such evidence lacks substantial similarity to Plaintiff's case; risks unfair prejudice, confusion, and delay; is inadmissible hearsay; and is inadmissible under Federal Rule of Evidence 703. (*Id.* at PageID #11929–36.) They also argue that the MDRs are inadmissible as matter of law pursuant to 21 U.S.C. § 360i(b)(3). (*Id.* at PageID #11937.) Plaintiff responds that he intends to use this evidence to demonstrate Defendants' state of mind, knowledge, and notice and does not otherwise indicate that any of his experts plan to rely on this evidence. (PageID #158548–49.) Accordingly, this opinion addresses only the impact of § 360i(b)(3) upon the MDRs, and the role of the substantial-similarity inquiry and Rule 403 upon the MDRs and other AERs.

1. Section 360i(b)(3)

Section 360i sets forth a mandatory record-keeping and reporting scheme to the FDA. Subsection (a) requires medical device manufacturers and importers to maintain records and make reports under certain circumstances. § 360(i)(a). For example, a manufacturer or importer must make a report to the FDA when a device "may have caused or contributed to a death or serious injury, or," if the device is "a class II device that is permanently implantable," as the Ventralight ST is, the device has malfunctioned. *Id.* at § 360i(a)(1). Subsection (b), on the other hand, sets forth when a device user facility, such as a hospital or nursing home, must make a report to the FDA. *Id.* at § 360i(b)(1); *see id.* at § 360i(b)(6)(A) (defining a "device user facility").[5]

[5] Part 803 of Title 21 of the Code of Federal Regulations provides further explanation, designating all such reports as MDRs. *See, e.g.*, 21 C.F.R. § 803.1(a); *see also* FDA, *Medical Device Reporting*

The protection and privacy of device user facilities appears to have been an important consideration for Congress in passing § 360i(b) in order to incentivize facilities to make such reports. *Butler v. Aaron Med. Indus., Inc.*, No. C03-00896 HRL, 2004 WL 7330072, at *4 (N.D. Cal. Oct. 21, 2004). Section § 360(b)(2) expressly forbids the Secretary of the FDA from disclosing the identity of a reporting device user facility. And, at issue here, subsection (b)(3) provides that no reports made by the device user facility, an employee or affiliate of a device user facility, or "a physician who is not required to make such a report" "shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report." § 360i(b)(3).

Defendants argue that all evidence of MDRs must be excluded under this provision, (ECF No. 213 at PageID #11937), and Plaintiff argues that all evidence of MDRs are admissible because this provision does not apply to medical device suits against the device manufacturer, (ECF No. 285 at PageID #15851–52.) Both sides misinterpret the statute and fail to distinguish between the types of MDRs Plaintiff could offer at trial—those from manufacturers, device user facilities, and health professionals.

Manufacturer reports are not addressed by § 360i(b), but § 360i(a). Accordingly, manufacturer MDRs are admissible insofar as § 360i(b)(3) does not apply to them. Though no binding precedent is on point, the vast majority of courts to consider this question or similar ones have reached the same interpretation of § 360i(b)(3). *See Coolidge v. United States*, No. 10-CV-

(MDR): How to Report Medical Device Problems, https://www.fda.gov/medical-devices/medical-device-safety/medical-device- reporting-mdr-how-report-medical-device-problems#overview (last visited Nov. 9, 2020). Anyone other than those persons and entities described in § 360i, such as a patient, may voluntarily report issues through the FDA's MedWatch program. *TMJ Implants v. U.S. Dep't of Health & Human Servs.*, 584 F.3d 1290, 1295–96 (10th Cir. 2009).

363S, 2018 WL 5919088, at *2 (W.D.N.Y. Nov. 13, 2018) (citing cases); *Kubicki ex rel. Kubicki v. Medtronic*, 307 F.R.D. 291, 298 (D.D.C. 2014) (considering discoverability rather than admissibility); *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, Nos. 2:12-MD-02327, 2:12-cv-4301, 2014 WL 505234, at *5 (W. Va. Feb. 5, 2014) (citing *Chism v. Ethicon Endo-Surgery, Inc.*, No. 4:08CV00341-WRW, 2009 WL 3-66679, at *1 (E.D. Ark. Sept. 23, 2009)).

Defendants provide no persuasive authority to the contrary. They cite the Eighth Circuit in *In re Medtronic, Inc.*, but the court was clear there that it considered user facility reports—not manufacturer reports, as are present here. 184 F.3d 807, 811 (8th Cir. 1999). Defendants also cite in *Adcox v. Medtronic, Inc.*, but there the court considered not the admissibility but discoverability of the device user facility reports, concluding that manufacturer reports are subject to discovery. 131 F. Supp. 2d. 1070, 1075 (E.D. Ark. 1999).

It is clear, however, that reports made by device user facilities pursuant to § 360i(b)(1) are inadmissible. The text of § 360i(b)(3) is plain: "No report made under paragraph (1) by" a device user facility, an employee or affiliate of a device user facility, or a physician who is not required to make such reports "shall be admissible into evidence or otherwise used in *any* civil action." § 360i(b)(3) (emphasis added). Although this provision provides an exception for when reporters otherwise covered by § 360i(b)(3) have personal knowledge of false information contained in reports, *id.*, those circumstances are not present here.

Plaintiff relies on *Contratto v. Ethicon*, 225 F.R.D. 593 (N.D. Cal. 2004), but fails to persuade. In *Contratto*, the district court concluded that user facility reports were discoverable, but also spoke to the admissibility of user facility reports, concluding that the reports were admissible because § "360i(b)(3) does not apply to a suit by a patient against the manufacture of the product that is the subject of the report." 225 F.R.D. at 596. This interpretation ignores the clear text of §

360(b)(3) that such reports are inadmissible "in any civil action." §360i(b)(3). Moreover, to reach this conclusion the court focused exclusively on regulations, legislative history, legislative purpose, and policy considerations germane to discovery of reports, but not their admissibility. *Id.* at 596–98. Crucially, the Sixth Circuit has been painstakingly clear that consideration of the legislative history, purpose, and policy of a statute is inappropriate when the meaning of the words is plain. *See Hughes v. McCarthy*, 734 F.3d 473, 478 (6th Cir. 2013). Even if the Court agreed with *Contratto*'s textual interpretation, the court in *Contratto* did not intend for its interpretation of § 360i(b)(3) to apply to MDRs because "MDRs are not covered" by § 3609(b)(3). 225 F.R.D. at 598 n.10.

In sum, this portion of Defendants' motion is denied in part and granted in part. MDRs submitted by manufacturers, including Defendants, are not inadmissible under § 360i(b)(3), though MDRs falling within the terms of the provision are inadmissible. A few words of warning, nevertheless, are warranted. Plaintiff's in camera proffer contains only MDRs made only by manufacturers. Therefore, it is unclear how a device user facility, employee, or physician making a voluntary report would be designated on the MDR. But the burden of showing admissibility of evidence is on its proponent. *United States v. Brika*, 416 F.3d 514, 529 (6th Cir. 2005). Thus, even if only to show notice or knowledge, Plaintiff must be able to show that the MDRs do not fall within the terms of § 360i(b)(3).

2. Substantial-Similarity Test

AERs and MDRs that are not inadmissible under § 360i(b)(3) must still satisfy the substantial-similarity test. *Chism*, 2009 WL 3066679, at *1. Prior accidents or incidents "must be 'substantially similar' to the one at issue before they will be admitted into evidence." *Rye v. Black & Decker Mfg. Co.*, 889 F.2d 100, 102 (6th Cir. 1989). Typically, this requires "that the accidents

must have occurred under similar circumstances or share the same cause." *Id.* Evidence of prior incidents may demonstrate that a defendant was on notice or had knowledge of the risks giving rise to the incident. *E.g.*, *Koloda v. Gen. Motors Parts Div., Gen. Motors Corp.*, 716 F.2d 373, 375–76 (6th Cir. 1983). When introduced to demonstrate notice or knowledge, "a lesser degree of similarity [than substantial similarity] is required provided the accident would have tended to warn the defendant." *Surles ex. rel. Johnson v. Greyhound Lines, Inc.*, 474 F.3d 288, 298 (6th Cir. 2007) (quoting *Bryan v. Emerson Elec. Co., Inc.*, 856 F.2d 192, 1988 WL 90910, at *5 (6th Cir. 1988) (unpublished table decision)) (upholding district court's application of the "lesser degree of similarity" on abuse-of-discretion review); *Mahaney el rel. Estate of Kyle v. Novartis Pharms.*, 835 F. Supp. 2d 299, 312 (W.D. Ky. 2011) ("[C]ourts typically impose the yard stick of 'substantial similarity' to ferret out those [prior incidents or accidents] that could not be expected to raise the manufacturer's awareness."); *cf. Rye*, 889 F.2d at 102 (applying the substantial-similarity test when plaintiff sought to introduce prior incidents as evidence of notice and causation). It is clear that neither "great specificity," *Surles*, 474 F.3d at 297, nor perfectly identical circumstances, *Rye*, 889 at 102, are required to show substantial similarity.

Defendants argue for a standard that is too exacting. Defendants urge the Court to admit only MDRs, AERs, or other complaints where the patient has an identical medical background. (ECF No. 213 at PageID #11930.) For example, they point to Plaintiff's obesity, diabetes, age, location of the mesh placement, type of repair procedure, and the existence of a device with ST coating. (*Id.* at PageID #11930–31.) For the purpose of knowledge, mindset, and notice, this is much more than substantial similarity. And predictably, neither the redacted MDR information, presented by Plaintiff via MAUDE database reports, nor the unredacted information presented by Defendant from its internal complaint file database, TrackWise, contains all of this information.

The level of detail in the patient's medical-history information is typically where the reports fall short. The inclusion of a patient's age or weight in event reporting would enable the jury to draw more meaningful conclusions from the MDRs. However, this level of granular medical history is unnecessary to show that Defendants were aware of risk presented by the Ventralight ST.

Accordingly, this portion of Defendants' motion is denied; the Court will not broadly exclude MDRs for a lack of substantial similarity at this moment. That being said, Plaintiff's proffer contains mostly MDRs that were made after the implantation of a Ventralight ST. Thus, these MDRs are irrelevant to notice. *Surles*, 474 F.3d at 298 ("The relevance of similar incidents depends in part on their proximity in time to the incident at issue in the case before the court.") (considering whether other incidents were evidence of notice). But at trial, Plaintiff may offer MDRs, AERs, and other complaints that are substantially similar to Plaintiff's experience. Based on the information before it, the Court preliminarily concludes that substantial similarity will be met if an MDR, AER, or complaint indicates that (1) the patient had the same injury as Plaintiff—adhesions, (2) the Ventralight ST or another ST device was implanted, (3) the repair was made to a hernia or other similar, abdominal soft-tissue injury; and (4) the repair method was laparoscopic, unless Plaintiff can show that open surgeries pose the same risk of adhesions as laparoscopic surgeries. Of course, Defendants are free to attack these prior incidents on the basis that the circumstances are not adequately similar to give notice. *Coolidge v.*, 2018 WL 5919088, at *3. But any details beyond what is required of the substantial-test similarity test for notice go to the weight, not admissibility, of the prior-incident evidence. *Id.*

3. Rule 403 and Other Issues

Defendants argue that evidence of other incidents will unfairly prejudice them at trial, confuse the jury, and delay the trial. (ECF No. 213 at PageID #11932.) At this time, it is uncertain

how Plaintiff plans to present evidence of the MDRs, AERs, and other complaints, and in what volume. If Plaintiff plans to rely on the number of MDRs, AERs, etc. or summaries of them and admits the reports only to show the underlying support, Defendants will not be *unfairly* prejudiced because the evidence is probative of their state of mind. However, if Plaintiff intends to produce dozens of MDRs and to walk through them, the mini-trial concern looms. For this reason, the Court will deny this portion of Defendants' motion at this time.

It is also important to note that although Plaintiff's in camera proffer complicated this decision, Plaintiffs technically complied with the terms of the Court's order, though Defendants argue otherwise. (ECF No. 350 at PageID #18693–94.) "The Court ordered Plaintiff to submit a sample of [MDRs]," and this order did not specify whether the sample was for the Court's general information or to see evidence that Plaintiff would actually seek to admit. (ECF No. 332 at PageID #17887.) Though the latter would have been most helpful, the Court cannot say that Plaintiff did not comply. Defendants also argue that MAUDE reports, which Plaintiff submitted, are not MDRS. (ECF No. 350 at PageID #18693.) Yet most courts consider MAUDE reports as synonymous with MDRs. *Butler*, 2004 WL 7330072, at *3 n.2 ("The universe of documents that comprise 'MDRs' is not clear, although the parties indicated at the pretrial conference that "MDR" also includes 'Maude Event Reports.'" (citation omitted)).

Regardless of Plaintiff's compliance, much of this opinion and order will likely require a second pass when Plaintiff puts forth its MDR evidence. For these reasons, as well as those set forth above, the Court declines to broadly exclude all evidence of MDRs, AERs, and other complaints.

C. Plaintiff's Motion in Limine No. 23

In his next motion in limine, Plaintiff argues that evidence of or reference to Defendants'

hernia mesh products as "lifesaving devices" or devices that lower the risk of complications, the number of devices sold, and the number of devices implanted in patients should be excluded. (ECF No. 247 at PageID #13136.) Defendants counter that referring to the Ventralight ST as lifesaving is appropriate and that number of Ventralight ST sales and implantations is admissible. (ECF No. 279 at PageID #14661–67.)

First, Plaintiff specifically contends that reference to the Ventralight ST as a lifesaving device is inadmissible because Defendants lack reliable data to support this label. (ECF No. 247 at PageID #13140.) Without much fussing, federals courts have permitted "lifesaving" characterizations if there is some evidence in the record to support the label. *See, e.g.*, *Keen v. C.R. Bard, Inc.*, No. 13-5361, 2020 WL 4818801, *4 (E.D. Pa. Aug. 19, 2020); *In re Bard IVC Filters Prods. Liab. Litig.*, Nos. MDL 15-02641-PHX-DGC, CV-16-00474-PHX-DGC, 2018 WL 1109554 (D. Ariz. Mar. 1, 2018). Defendants point to no such evidence here. They cite Dr. Grischkan's testimony, but Dr. Grischkan did not testify that hernias may cause death if left untreated. Instead, this portion of his testimony focused on the existence of "deadly complications" resulting from hernia mesh repair surgeries—both with and without mesh. (ECF No. 279-3 at PageID #14689–90, pp. 395–98.) Thus, this portion of Plaintiff's motion in limine is granted. If Defendants can point to testimony that stands for the proposition that untreated hernias may cause death, the Court will revisit this ruling.

Next, Plaintiff argues that evidence of the number of Ventralight ST devices implanted and sold is inadmissible to prove safety. (ECF No. 247 at PageID #13140, 13143.) Specifically, Plaintiff argues that any number of Defendants' sales and implantations are unreliable, presumably when compared to the number of incident reports discussed later in this opinion, because Defendants cannot determine the outcome of or the medical history of each person implanted with

the device that did not suffer an adverse event. (*Id.*) Therefore, Defendants cannot satisfy the substantial-similarity test set forth *supra* in Part III.B.2. (*Id.*) Defendants make clear, however, that they intend to introduce this type of evidence, the low number of adverse events in comparison to the number of Ventralight STs sold and implanted, to prove their state of mind and knowledge. (ECF No. 279 at PageID #14663–64.) Defendants will introduce these numbers to show that they reasonably believed that the Ventralight ST was safe given the numbers they were aware of. (*Id.*)

Generally, Plaintiff is correct—the proponent of evidence of a lack of prior incidents or accidents bears the burden of showing that the lack of prior incidents occurred under substantially similar conditions, as when evidence that prior incidents occurred is introduced. *E.g.*, *Hines v. Joy Mfg, Co.*, 850 F.2d 1146, 1154 (6th Cir. 1988); *see also Koloda*, 716 F.2d at 375. But as set forth above, a less exacting version of substantial similarity will survive appellate review when the proponent of the evidence of an absence of prior events offers it to demonstrate knowledge, notice, or mindset. *See Surles*, 47 F.3d at 297–98.

Nevertheless, Plaintiff casts his net much too wide. General figures are routinely admitted in civil cases without forcing the proponent of the number to point to each person serving as a datapoint and prove substantial similarity. Indeed, Plaintiff fails to provide a case where a Court has required this prior to the admission of high-level, general numbers. This requirement would be incredibly burdensome and render the admission of most statistics and figures unfeasible. It makes sense then that the Sixth Circuit appears to apply a very relaxed version of the substantial-similarity test to figures and statistics. In *Morales v. American Honda Motor Co.*, it was enough that the accident statistics, of both adults and children, encompassed "vehicles [that] perform a similar purpose" when the case at hand considered the cause of a child's injury while riding a motorbike. 151 F.3d 500, 511–12 (6th Cir. 1998). Under the logic of *Morales*, Defendants clear

this bar.[6] All figures pertain to the Ventralight ST and Defendants had knowledge of these numbers at the time of Plaintiff's implantation. (ECF No. 279 at PageID #14663.)[7]

Plaintiff is entitled to challenge the weight of these overall numbers by making these arguments here to the jury. However, the number of devices sold and implanted is historical in nature and not particularly meaningful to either side without additional argument and context. These numbers are part of the story of the Ventralight ST. *Old Chief v. United States*, 519 U.S. 172, 189 (1997).[8]

Accordingly, Plaintiff's motion is granted in part and denied in part. Defendants also argue that the number of Ventralight STs implanted and sold gives context to the number of complaints that Plaintiff will point to at trial, generating a complaint rate. (ECF No. 279 at PageID #14664.) This argument is best addressed along with Plaintiff's Motion in Limine No. 7 below.

D. Plaintiff's Motion in Limine No. 7

In this motion in limine, Plaintiff argues that any percentages or comparative analysis of adverse events should be excluded. (ECF No. 243 at PageID #13074.)[9] Plaintiff argues that the AHSQCF and FDA reports are unreliable on their own, as well as that Defendants' method of taking the incidents of Ventralight ST failure and dividing that number over the total number of sales and/or implantations of the Ventralight ST results is unreliable and prejudicial evidence of

[6] As Defendants point out, some courts avoid applying the substantial-similarity test all together. E.*g.*, *Tran v. Toyota Motor Corp.*, 420 F.3d 1310, 1316 (11th Cir. 2005). This is not the approach in this circuit, however.

[7] If the Court were to adopt Plaintiff's approach, it is unclear why the AHSQCF data, which Plaintiff seeks to admit, *supra* Part III.A, would be admissible without a showing of substantial similarity. Under Plaintiff's own logic, he would need to demonstrate all patients serving as datapoints suffered incidents that were substantially similar to Plaintiff's experience.

[8] Because this part of Plaintiff's motion is denied, there is no need to address the propriety of Plaintiff's discussion regarding Dr. Renton's opinion. (ECF No. 279 at PageID #14667–68.)

[9] In its previous motions in limine opinion and order, the Court adjudicated Defendants' and AHSQCF's motions to seal an AHSQCF report. (ECF No. 359 at PageID #18785.) This report was attached to Plaintiff's Motion in Limine No. 9, which was decided on the merits (*id.*), but the Court expressly reserved its decision on the merits regarding Plaintiff's Motion in Limine No. 7, (*id.* at PageID #18786 n.4).

comparative risk. (*Id.* at PageID #13075.) Defendants counter that if the Court permits adverse event data, then they should be permitted to introduce not only the overall sales and implant numbers, but also their calculation of an adverse event rate. (ECF No. 263 at PageID #14022–23.) Alongside this motion, the Court considers Defendants' argument that Plaintiff's percentages from the AHSQCF data are also unreliable and without context. (ECF No. 338-2 at PageID #18491); *see supra* Pages 10–11.

As a preliminary matter, Plaintiff's positions here and in opposition to AHSQCF's motion in limine are somewhat confounding. In his opposition to AHSQCF's motion, he asserts that "[t]he [AHSQCF] reports go directly 'to the heart of Plaintiff's claims concerning Defendant's knowledge.'" (ECF No. 200 at PageID #11620 (citation omitted).) But here, he argues that the AHSQCF (as well as FDA) adverse event reports are beleaguered with issues, such as bias, under reporting, incomplete reports, and "inadequate long-term follow-up." (ECF No. 243 at PageID #13078.) Plaintiff's counsel attempted to reconcile these positions during a status conference, explaining that Plaintiff's Motion in Limine No. 7 "solely pertains to the way Bard presents its adverse event data," *i.e.* by creating a rate or percentage. (ECF No. 311 at PageID #16822.) The motion clearly does more than that. Plaintiff's Motion in Limine No. 7 attacks the quality of the AHSQCF reports themselves—not just Defendants' approach to creating a rate of adverse event reports. Even if Plaintiff pointed to different AHSQCF reports here (and it is not clear that he does), such critiques would appear to apply to all AHSQCF data.

In that vein, Plaintiff's arguments that the AHSQCF and FDA adverse event reports are faulty are to no avail. The earlier analysis regarding the relevance and prejudicial effect of the AHSQCF data, *see supra* Part III.A, applies with equal force here. Shortcomings of AHSQCF data go to the weight of the evidence, not admissibility. *Weinstock*, 153 F.3d at 278; *see also Obrey*,

400 F.3d at 695. Plaintiff provides only a cursory assertion that that the AHSQCF reports have certain weaknesses. (ECF No. 243 at PageID #13078.) Therefore, the Court cannot discern why its ruling here should be any different than its ruling on AHSQCF's motion in limine. Additionally, Plaintiff pays scant attention to the FDA reports in his briefing, again only providing brief assertions that the FDA reports are imperfect. (*Id.*) Plaintiff provides no basis for reaching a different conclusion for the FDA reports. Plaintiff may challenge the reports, highlighting for the jury their inadequacies. And with the challenges that Plaintiff is sure to mount, there is no undue risk of prejudice, confusion, or misleading the jury under Rule 403.

Like AHSQCF, Plaintiff points to cases addressing the reliability of information in the expert witness context, such as *McClain v. Metabolife International, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005). *See also id.* at 1239 (considering the expert opinion of James O'Donell). (ECF No. 243 at PageID #13079.) Reliability of an expert opinion is not the same as relevance. *See* Part III.A.

Plaintiff next argues that Defendants' adverse event rate is irrelevant or unduly prejudicial. To reiterate Defendants' position, this rate is comprised of the AHSQCF and FDA adverse event numbers and the total number of Ventralight ST sales and implantations. It is unclear how Defendants seek to admit this evidence. There is no indication that Defendants seek to have an expert testify as to a complication rate. And if a corporate witness seeks to testify that at the time of Plaintiff's surgery Defendants knew of a complaint or adverse event rate that was calculated by Defendants in the same manner, then this is admissible evidence of Defendants' knowledge. Fed. R. Evid. 701(a).

But Defendants appear to offer something different—a counsel-created, post-hoc adverse event rate to be used during argument. A complaint rate such as this is certainly relevant, but its

admission would unduly prejudice Plaintiff and mislead the jury. Neither Plaintiff nor Defendants cite a case addressing the admissibility of an adverse event rate outside of the context of expert testimony. *E.g.*, *In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*, 45 F. Supp. 3d 724, 732 (N.D. Ohio 2014). This makes sense because in the expert witness context, it is crucial that the opposing party can challenge the qualified *witness's* calculation of the rate. *E.g.*, *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993). Here, defense counsel cannot testify as an expert witness and be cross-examined so that their methodology can be dissected by Plaintiff's counsel. And there is no doubt that statistics lend an air of scientific reliability, which is inappropriate outside of the expert witness context. Although this result may at first seem strange because the component pieces of evidence that form the adverse event rate, the number of adverse events and the number of Ventralight ST's sold and implanted, are admissible, this appearance of reliability justifies exclusion under Rule 403. Accordingly, Defendants will only be permitted to introduce their adverse event rate through a qualified witness who was subject to vigorous cross examination. The same reasoning holds for Plaintiff's statistics created using the AHSQCF data. The jurors will not, presumably, have any personal knowledge as to what is or what is not a high or a low adverse incident rate. Closing argument may not be used by either side to argue statistics, rates, or other similar matters not adduced as evidence from a qualified witness.

Defendants point to cases addressing a lack of prior incidents (ECF No. 263 at PageID #14025), but these cases provide no support. Nothing in prior-event cases, including the absence of prior event cases, speak to the presentation of rates or percentages based on underlying numbers of events or nonevents. *See generally* Part III.C.

Defendants also argue that they will be unfairly prejudiced if they cannot present evidence of their adverse event rate. (ECF No. 263 at PageID #14024–25.) But the AHSQCF reports, FDA

reports, AERs, and MDRs are admissible along with the sales and implant numbers of the Ventralight ST. Therefore, Defendants will be able to contextualize the adverse event reports to the jury, which is the key concern Defendants present in their briefing. (*Id.* at PageID #263 at PageID #14022.) If a complication rate is not going to be admitted as a figure known by Defendants at the time of Plaintiff's surgery or through expert testimony, the path forward is to allow the figures in evidence to speak for themselves.

For this reason, Plaintiff's motion is granted in part and denied in part.

IV. Conclusion

Accordingly, AHSQCF's Motion in Limine (ECF No. 180) is **GRANTED IN PART AND DENINED IN PART**, Defendants' Motion in Limine No. 12 (ECF No. 213) is **DENIED**, Plaintiff's Motion in Limine No. 23 (ECF No. 247) is **GRANTED IN PART AND DENIED IN PART**, and Plaintiff's Motion in Limine No. 7 (ECF No. 243) is **GRANTED IN PART AND DENIED IN PART**.

IT IS SO ORDERED.

12/3/2020
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE